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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,585	06/08/2000	Simon J. Mantell	PC10334A	1013

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EXAMINER	
YOUNG, JOSEPHINE	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/590,585	MANTELL ET AL.	
	Examiner	Art Unit	
	Josephine Young	1623	

-- The MAILING DATE of this communication appears on th cover sh et with the correspondence address --

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003 and 18 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,4,5* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *11* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the species defined in Example 1, page 32 of the specification, in Paper No. 10, mailed March 10, 2003, is acknowledged. Applicant's arguments for traversal have been considered and have overcome the requirement for the election of species as set forth in the Office Action of February 11, 2003.

Amendments filed November 18, 2002 and March 10, 2003

In the amendment filed November 18, 2002, claims 19-24 were cancelled. Claims 4, 5, 8-10, 13, 18, 25-27, 29, 31 and 33 were amended. Claims 41 and 42 were added.

In the amendment filed March 10, 2003, claims 25-29 and 31-42 were cancelled.

An action on the merits of claims 1-18 and 30 is contained herein below.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The papers submitted under 35 U.S.C. 119(a)-(d) have been placed of record in the file.

Acknowledgment is made of applicant's claim for domestic priority under 35 U.S.C. 120 and 365(a)-(c). However, Applicant has not complied with one or more conditions for receiving

the benefit of the filing date of international application PCT/IB00/00789 designating the United States under 35 U.S.C. 120 and 365(a)-(c) as follows:

> This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required.

The present application was filed June 8, 2000, prior to the filing date of the international application PCT/IB00/00789, filed June 13, 2000. Therefore, the present application could not have been co-pending with the international application at the time of filing of the present application, as the international application had not yet been filed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 1-18 and 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10 of U.S. Patent No. 6,525,032 to MANTELL et al. (A) in view of JACOBSON et al., Journal of Medicinal Chemistry, **1992**, *35*

(3), 407-422 (U). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentable distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Specifically, claims 1-6 of U.S. Patent No. 6,525,032 are directed to 5'-uronamide adenosine derivatives, wherein A can be a C_1-C_6 alkylene, R^2 can be NR^3R^3 and R^3 can be H, C_1-C_6 alkyl, phenyl or pyridinyl. Claim 7 of U.S. Patent No. 6,525,032 is directed to pharmaceutical compositions containing such compounds. Claim 10 of U.S. Patent No. 6,525,032 is directed to particular synthetic intermediates for obtaining the compounds of claim 1 of U.S. Patent No. 6,525,032.

Claims 1-7 and 10 of U.S. Patent No. 6,525,032 do not recite the unprotected hydroxymethyl derivatives. Further, claims 1-7 and 10 of U.S. Patent No. 6,525,032 do not recite any possible synthetic process to arrive at the compounds as defined by claim 1 of the present application.

JACOBSON teaches that the unprotected hydroxymethyl adenosine derivatives and 5'-uronamide adenosine derivatives are agonists of adenosine A2 receptors. See Table II, pages 410-411.

It would have been obvious to one of ordinary skill in the art to make and use the unprotected hydroxymethyl derivatives of the 5'-uronamide derivatives of claims 1-7 of U.S.

Patent No. 6,525,032. A skilled artisan would have been motivated and had a reasonable expectation of success to use the unprotected hydroxymethyl adenosine derivatives to agonize adenosine A2 receptors, as JACOBSON teaches that such derivatives are also A2 receptor agonists. Further, claim 30 of the present application is directed to a process for the preparation of the compounds using standard synthetic manipulations. While the claims in U.S. Patent No. 6,525,032 do not teach any process for the preparation of the compounds of claims 1-6, it would have been obvious to one of ordinary skill in the art to make the compounds of claim 1-6 of U.S. Patent No. 6,525,032 in any way well known in the art, for example via an intermediate as recited in claim 10. Substitution on an aromatic ring, deprotection of a sugar and condensation of a carboxylic acid to form an amide are well known to a skilled artisan in the field of organic synthesis, and are considered well within the purview of the prior art.

Claims 1-17 and 30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 63 of copending Application No. 09/874,007. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentable distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Specifically, claim 63 of copending Application No. 09/874,007 is directed to adenosine derivatives, wherein X can be a C_2-C_3 alkylene, R^2 can be H or C_1-C_6 alkyl, R^{15} can be H or C_1-C_6 alkyl, and R^5 can be CH_2OH. Therefore, the specific sub-generic compound of claim 63 of copending Application No. 09/874,007 overlaps with the generic compound recited in claim 1 of the present application. Furthermore, all of the limitations recited in dependent claims 2-17 of the present application are within the limitations of the sub-generic compound of claim 63 of copending Application No. 09/874,007. That is claims 1-17 are rendered obvious by claim 63 of copending Application No. 09/874,007.

Further, claim 30 of the present application is directed to a process for the preparation of the compounds using standard synthetic manipulations. While the claims in copending Application No. 09/874,007 do not teach any process for the preparation of the compound of claim 63, it would have been obvious to one of ordinary skill in the art to make the compounds of claim 63 of copending Application No. 09/874,007 in any way well known in the art. Substitution on an aromatic ring, deprotection of a sugar and condensation of a carboxylic acid to form an amide are well known to a skilled artisan in the field of organic synthesis, and are considered well within the purview of the prior art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Prior Art

The closest prior art with respect to the present invention appears to be the review article JACOBSON et al., J. Med. Chem., 1992, 35 (3), 407-422 (U). However, JACOBSON does not specifically teach the compounds of the present invention or the use of such compounds. Therefore, the claims appear to be free of the prior art.

Conclusion

Claims 1-18 and 30 are pending. Claims 1-18 and 30 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY
May 30, 2003

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600